

REMARKS

The above claim amendments are submitted along with the following remarks to be fully responsive to the outstanding Office Action mailed July 2, 2004. It is further submitted that this response is timely filed within the shortened statutory period as extended by the One-Month Request for Extension of Time concurrently filed herewith. Reconsideration of all outstanding grounds of objection and rejection and allowance of the subject application are respectfully requested.

Specification

The specification was amended to correct a typographical error in a listed patent number in the original application that was noted in review of the application by the Applicants. It is evident that the newly listed patent number is correct because the incorrect U.S. Patent No. 4,566,466 relates to a surgical instrument for performing an anterior cervical interbody arthrodesis, and the correct U.S. Patent No. 4,566,446 relates to a penile prosthesis device that is described in the specification of the application and in the Office Action. In addition, Applicants listed this patent number correctly in the form PTO-1449 filed on May 4, 2003. No new matter was added.

Claim Rejections

Claims 16 and 17 were rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements. In response, claims 16 and 17 have been amended to better define the relationship between the pump bulb and the housing. Thus, the rejection of claims 16 and 17 under 35 U.S.C. § 112 is overcome.

Amendments were also made to claims 1 and 3 in a similar manner to the amendments to claims 16 and 17 discussed above. These amendments to claims 1 and 3 also better define the relationship between the pump bulb and the housing in these claims. In addition, claims 1, 3, 16, and 17 have been amended to define the pump bulb as compressible, as is well known in the art of pump assemblies for penile prostheses, and as is described throughout the specification relative to the squeezing and/or compression of the pump bulb when using the device. For example, paragraph [0016] describes the

pump bulb as being “squeezable through tissue” and that certain movements are resisted when “the pump bulb is squeezed”. Thus, no new matter is added.

Claims 1-18 were rejected under 35 U.S.C. §102(e) as being anticipated by Almli et al. (U.S. Patent No.6,723,042; herein referred to as “Almli”). Applicants respectfully disagree. Almli discloses a pump and valve assembly including a valve housing fluidly coupled to a pump bulb. The valve housing is configured so that it can be grasped by the user to actuate the valve components, such as by compression of the valve housing. The valve housing is described as including a textured surface to help the patient to identify the correct portion of the pump and valve assembly to grasp for actuation and to prevent slippage once the patient begins to compress the housing. Further, Almli specifically discusses the importance of having a pump bulb that is “differentiated from the valve housing when inflation of the cylinders is desired” (col. 3, lines 23-25) and further recognizes that a textured surface is thus provided on the valve housing so that the patient can easily differentiate the area that comprises the valve housing and the area that comprises the pump bulb. Almli does not disclose using such textured surfaces on the pump bulb.

In contrast, independent claims 1, 3, 16, and 17 of the present application recite a pump assembly including *a pump bulb* having plurality of protrusions. Thus, the present claims 1, 3, 16, and 17, and their corresponding dependent claims 2 and 4-15, are patentably distinct from Almli at least in that Almli does not disclose a pump bulb having a plurality of protrusions. Further, with regard to claim 18, Almli does not disclose a bar shaped housing having end portions and side portions, with each end portion having at least one protrusion and the side portions having a side bar, as is recited in claim 18. Thus, claim 18 is also patentably distinct from Almli. In addition, while claims 1-18 are believed allowable as submitted herein, to the extent that the Examiner believes there are any issues relative to obviousness, any subject matter developed by the inventors of Almli which qualifies as “prior art” under 35 U.S.C. §102(e) is not to be considered for obviousness purposes under 35 U.S.C. §103, since the subject matter and the claimed invention were commonly owned at the time the invention was made.

Next, claims 1-18 were rejected under 35 U.S.C. §103(a) as unpatentable over Ripple et al. or Fogarty in view of Wong. Applicants note that the references made to the

Ripple et al. reference as U.S. Patent No. 4,566,466 were incorrect in both paragraph [0004] of the present application as submitted, and on the Examiner's form PTO-892. These documents should have instead referred to that reference as U.S. Patent No. 4,566,446, which is issued to Fogarty. Thus, the references made to the Ripple et al. patent throughout the Office Action will instead be referred to herein as the Fogarty '446 patent. For clarity, the references made in the Office Action to the Fogarty patent (U.S. Patent No. 4,537,183) will be referred to herein as the Fogarty '183 patent. That is, the present rejection would instead be a rejection of claims 1-18 under 35 U.S.C. §103(a) as unpatentable over Fogarty '446 or Fogarty '183 in view of Wong. In particular, the Examiner states that a modification of either Fogarty reference to include the gripping means of Wong would have been obvious.

The rejection of claims 1-18 is traversed as failing to support a conclusion of *prima facie* obviousness. Specifically, the Office Action does not include an adequate showing of the requisite suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings to produce a device of the invention as claimed.

According to the Office Action, Fogarty '446 and Fogarty '183 both disclose implantable penile prosthesis having a pump with ridges and grooves to prevent slippage during use, and Wong is said to disclose a grip (26) that has a plurality of protrusions and grooves that are discrete, discontinuous, and spaced apart to aid in gripping the device. First, these references are not combinable in that the Wong reference is directed to an all-purpose ratchet screwdriver, which is in contrast to the compressible pumps of the Fogarty references as part of an implantable medical device. The screwdriver of Wong is intended to be used as a mechanical tool that can be gripped by the hand of a user and rotated. In contrast, the pumps of the Fogarty references are designed for implantation within the scrotal sac of a patient, where any gripping of the outer surface of the pump is done through the tissue and fluids of the scrotal sac. Such distinctly different devices function in entirely distinct manners and are handled in entirely distinct ways, and as such, have little, if any, relevance to one another as to gripping surfaces used to prevent any type of slippage between surfaces. Thus, these references are not combinable based upon their well-established distinction in the art.

Secondly, Wong does not suggest any reason for the grip section of its device to be compressible. The clearly stated purposes of Wong's rubber sleeve are to enable "convenient gripping by a hand" (col. 2, lines 30-33) and to enable the invention of Wong to be "conveniently held in the hand and rotated" (col. 3, lines 42-44). Thus, the rubber sleeve of Wong is designed for a user to hold or grip around the circumference of the grip section in order to rotate the screwdriver in a particular manner. This use of the rubber sleeve is entirely dissimilar to the use of outer pump surfaces of either of the Fogarty references. Thus, there is no motivation to apply a surface structure of a sleeve for a screwdriver to the pumps used in the penile prostheses of either of the Fogarty references absent hindsight reconstruction. In addition, Wong does not suggest the use of its gripping surface inside a human's body, in conjunction with bodily fluids and tissues, which requires specific considerations that need not be taken into account for a surface that is gripped by a user's hand without intervening tissue and bodily fluids between the gripping surface and the hand.

Next, while both Fogarty '446 and Fogarty '183 show pump bulbs having ridges that extend continuously around their circumferences, there is no suggestion that their pumps instead be provided with a different pattern of ridges. In particular, there is no suggestion in either of the Fogarty references to instead use a pump having a plurality of protrusions that are discontinuous, discrete, and/or spaced apart. Wong does nothing to cure this deficiency, at least in that one skilled in the art would not look to the screwdriver of Wong for modifying a pump in a penile prosthesis. That is, Wong is directed specifically to a multi-angle, all-purpose ratchet screwdriver having multiple pieces, including a grip section having a rubber sleeve fitted over the outer surfaces of the grip section. The pumps of the Fogarty references are not designed for such a gripping and rotating movement, but instead are designed to be repeatedly squeezed by a user through that user's tissue.


Thus, the Office action fails to offer a valid showing of a suggestion or motivation to combine the Fogarty references with the Wong reference, to result in a pump bulb as claimed in the present claims 1-17. In particular, each of independent claims 1, 3, 16, and 17 are believed allowable in that they include a pump bulb having the distinct features described above, and dependent claims 2 and 4-15 are likewise allowable at least

in that they depend from an independent claim that is believed allowable. With further regard to independent claim 18, the cited Fogarty references also fail to suggest an implantable prosthesis including a pump assembly having a bar shaped housing having end portions with at least one protrusion and side portions having a side bar. Wong does nothing to cure these deficiencies in that Wong is not even directed to pump assemblies with housings having protrusions. Thus, claim 18 is also believed allowable.

Accordingly, it is submitted that presently pending claims 1-18 are currently in condition for allowance, a notice of which is earnestly solicited. The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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